

Response dated June 9, 2005
Reply to Office Action dated February 9, 2005

Application No. 10/052,077

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. **(Original)** A flow control device for an implantable pump, the flow control device comprising:

- a) a reservoir for containing a pressurized supply of drug and a valve in fluid communication with the reservoir, the valve adapted to assume two flow states;
- b) a control module for generating a control signal to the valve to thereby cause the valve to assume one of the two flow states, the control module duty cycling the valve to achieve a desired average flow rate over time; and
- c) a bolus delivery component in fluid communication with the reservoir for metering and delivering a predetermined amount of drug bolus, the bolus delivery component further comprising an inlet valve, an accumulator, and an outlet valve, the bolus delivery component in parallel communication with the valve.

2. **(Original)** The flow control device of claim 1, further comprising a flow restrictor in fluid communication with the valve.

3. **(Original)** The flow control device of claim 1, wherein the valve is selected from the group consisting of: micro-machined bi-stable valves, solenoid valves, piezoelectric operated valves and shape memory alloy actuated valves.

4. **(Original)** The flow control device of claim 1, wherein the two flow states comprise an open state, permitting flow through the valve, and a closed state, preventing flow through the valve.

5. **(Original)** The flow control device of claim 1, wherein the valve is a bi-stable valve.

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6. **(Original)** A flow control device for an implantable pump, the flow control device comprising:

- a) a reservoir for containing a pressurized supply of drug and a valve in fluid communication with the reservoir, the valve being adapted to selectively permit flow of drug at two predetermined rates;
- b) a control module for generating a control signal to cause the valve to cycle between the two predetermined rates to achieve a desired average flow rate; and
- c) a bolus delivery component in fluid communication with the reservoir for metering and delivering a predetermined amount of drug bolus, the bolus delivery component further comprising an inlet valve, an accumulator, and an outlet valve, the bolus delivery component in parallel communication with the valve.

7. **(Original)** The flow control device of claim 6, further comprising a flow restrictor in fluid communication with the valve.

8. **(Original)** The flow control device of claim 6, wherein the valve is a micro-machined element.

9. **(Original)** The flow control device of claim 6, wherein the two flow states comprise an open state, permitting flow through the valve, and a closed state, preventing flow through the valve.

10. **(Original)** The flow control device of claim 6, wherein the valve is a bi-stable valve.

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11. **(Previously Presented)** A flow control device for an implantable pump, the flow control device comprising:

a) a reservoir for containing a pressurized supply of drug and a flow control assembly for providing a normal dosage flow rate of drug from the reservoir to a patient, the flow control assembly including a valve in fluid communication with the reservoir and a restrictor in fluid communication with the valve;

b) a bolus delivery component for metering and delivering a predetermined amount of drug bolus in addition to the normal dosage, the bolus delivery component further comprising an inlet valve, an accumulator, and an outlet valve, the bolus delivery device in parallel communication with the flow control assembly; and

c) a control module for providing control signals to the inlet valve and the outlet valve to permit an accumulation of drug within the accumulator

12. **(Original)** The flow control device of claim 11, wherein the bolus delivery device comprises an accumulator for accumulating a bolus of drug, an inlet valve for selectively permitting ingress of drug to the accumulator, and an outlet valve for selectively permitting egress of accumulated drug from the accumulator.

13. **(Cancelled)**

14. **(Previously Presented)** A device for controlling the flow rate of an implantable pump comprising a reservoir adapted to contain a volume of medicament under pressure, the flow rate control device comprising:

(a) a valve in fluidic communication with the reservoir, the valve being adapted to assume two flow states;

(b) a control module for producing a control signal sent to the valve to cause the latter to assume one of the two flow states, the control signal effecting cyclic control of the valve to obtain the desired mean flow rate over time; and

(c) a device for passively delivering a controlled bolus in fluidic communication with

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the reservoir for metering and delivering a predetermined quantity of bolus medicament, the device for delivering the bolus being in parallel communication with the valve.

15. **(Previously Presented)** The flow rate control device of claim 14, further comprising a flow restrictor in fluidic communication with the valve.

16. **(Previously Presented)** The flow rate control device of claim 14, wherein the valve is selected from the group consisting of: bistable macro-machined valves, electromagnetic valves, piezoelectrically actuated valves, and valves actuated by a shape memory alloy.

17. **(Previously Presented)** The flow rate control device of claim 14, wherein the two flow states comprise an open state, which allows flow through the valve, and a closed state, which prevents flow through the valve.

18. **(Previously Presented)** The flow rate control device of claim 14, wherein the valve is a bistable valve.

19. **(Previously Presented)** The flow rate control device of claim 14, wherein the bolus delivering device comprises:

- (a) an accumulator serving to accumulate the bolus of the medicament;
- (b) a first passive flow rate control element for controlling the introduction of the bolus from the reservoir into the accumulator;
- (c) a second passive flow rate control element for controlling the exit of the accumulated bolus from the accumulator;
- (d) means for controlling the operation of the first and second passive flow rate control elements to allow a predetermined bolus of medicament to accumulate in the accumulator and to allow the accumulated bolus to be released subsequently.

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20. **(Previously Presented)** The flow rate control device of claim 14, wherein the bolus delivering device includes an accumulator serving to accumulate the bolus of the medicament.

21. **(Previously Presented)** A flow rate control device for an implantable pump comprising a reservoir adapted to contain a volume of medicament under pressure, the flow rate control device comprising:

- (a) a valve in fluidic communication with the reservoir, the valve being adapted to allow a medicament to flow, as selected, at two predetermined flow rates;
- (b) a control module for producing a control signal serving to carry out cyclic control of the valve between the two predetermined flow rates to obtain a desired mean flow rate; and
- (c) a device for delivering a passively controlled bolus in fluidic communication with the reservoir for metering and delivering a predetermined quantity of bolus of medicament, the device for delivering the bolus being in parallel communication with the valve.

22. **(Previously Presented)** The flow rate control device of claim 21, further comprising a flow restrictor in fluidic communication with the valve.

23. **(Previously Presented)** The flow rate control device of claim 21, wherein the valve is a micro-machined element.

24. **(Previously Presented)** The flow rate control device of claim 21, wherein the two predetermined flow rates comprise a first flow rate corresponding to an open state, which allows flow through the valve, and a second flow rate corresponding to a closed state, which prevents flow through the valve.

25. **(Previously Presented)** The flow rate control device of claim 21, wherein the valve is a bistable valve.

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26. (Previously Presented) The flow rate control device of claim 21, wherein the bolus delivering device comprises:

- (a) an accumulator serving to accumulate the bolus of the medicament;
- (b) a first passive flow rate control element for controlling the introduction of the bolus from the reservoir into the accumulator;
- (c) a second passive flow rate control element for controlling the exit of the accumulated bolus from the accumulator;
- (d) means for controlling the operation of the first and second passive flow rate control elements to allow a predetermined bolus of medicament to accumulate in the accumulator and to allow the accumulated bolus to be released subsequently.

27. (Previously Presented) The flow rate control device of claim 21, wherein the bolus delivering device includes an accumulator serving to accumulate the bolus of the medicament.

28. (Previously Presented) The flow control device of claim 1, wherein the bolus delivering component comprises:

- (a) the accumulator serving to accumulate the bolus of the medicament;
- (b) a first passive flow rate control element for controlling the introduction of the bolus from the reservoir into the accumulator;
- (c) a second passive flow rate control element for controlling the exit of the accumulated bolus from the accumulator;
- (d) means for controlling the operation of the first and second passive flow rate control elements to allow a predetermined bolus of medicament to accumulate in the accumulator and to allow the accumulated bolus to be released subsequently.

29. (Previously Presented) The flow control device of claim 1, wherein the accumulator serves to accumulate the bolus of the medicament.

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30. **(Previously Presented)** The flow control device of claim 6, wherein the bolus delivering component comprises:

- (a) the accumulator serving to accumulate the bolus of the medicament;
- (b) a first passive flow rate control element for controlling the introduction of the bolus from the reservoir into the accumulator;
- (c) a second passive flow rate control element for controlling the exit of the accumulated bolus from the accumulator;
- (d) means for controlling the operation of the first and second passive flow rate control elements to allow a predetermined bolus of medicament to accumulate in the accumulator and to allow the accumulated bolus to be released subsequently.

31. **(Previously Presented)** The flow control device of claim 6, wherein the accumulator serves to accumulate the bolus of the medicament.

32. **(Previously Presented)** The flow control device of claim 11, wherein the bolus delivering component comprises:

- (a) the accumulator serving to accumulate the bolus of the medicament;
- (b) a first passive flow rate control element for controlling the introduction of the bolus from the reservoir into the accumulator;
- (c) a second passive flow rate control element for controlling the exit of the accumulated bolus from the accumulator;
- (d) means for controlling the operation of the first and second passive flow rate control elements to allow a predetermined bolus of medicament to accumulate in the accumulator and to allow the accumulated bolus to be released subsequently.

33. **(Previously Presented)** The flow control device of claim 11, wherein the accumulator serves to accumulate the bolus of the medicament.

34. **(New)** The flow control device of claim 1, further comprising an outlet, wherein the valve is positioned between the reservoir and the outlet.

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35. (New) The flow control device of claim 1, wherein the control module is further configured to generate a control signal to the bolus delivery component to operatively cause the bolus delivery component to delivery a bolus.